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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,714

03/22/2004

Wilhelmus Joseph Leonardus Suyker

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KNOBLE, YOSHIDA & DUNLEAVY

EIGHT PENN CENTER

SUITE 1350, 1628 JOHN F KENNEDY BLVD

PHILADELPHIA, PA 19103

EXAMINER

ANDERSEN, MICHAEL T

ART UNIT

PAPER NUMBER

3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/805,714

Applicant(s)

SUYKER ET AL.

Examiner

M. Thomas Andersen

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-41 is/are pending in the application.
- 4a) Of the above claim(s) 31-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/22/2004, 5/03/2004.

DETAILED ACTION

Priority

Acknowledgement is made of the claim to benefit of 371 application number pct/nl 98/00605, filed on 10/22/1998.

Information Disclosure Statement

The information disclosure statements (IDS) received on 3/22/20004 and 5/03/2004 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Election/Restrictions

Applicant's election with traverse of Group I, claims 15-30 in the reply filed on 11/21/2006 is acknowledged. The traversal is on the ground(s) that the method, as now claimed, cannot be performed with another material apparatus because the apparatus is enumerated in the method claim. This is not found persuasive because the other ground of restriction, namely the apparatus as claimed can be used to practice another and materially different process, e.g. stabilizing a heart valve with the applicator as claimed in claim 15. See MPEP 806.05(e). Further, as stated in the restriction requirement, the inventions are classified in different areas, and because of the different utilities of the method and apparatus there is a substantial burden on the examiner to examine both inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 15-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Dakov, U.S. 5,720,755.

Dakov discloses an applicator for use in a system including joining elements for making an anastomosis between hollow structures, said applicator comprising a head 202 provided with a plurality of arms 214, each said arm having a proximal end and a distal end, and wherein each said arm is movable from a first position (Fig. 12C) at which the distal ends of the arms are separated by a first distance which is less than a distance of separation between the proximal ends of said arms when said arms are in the first position, to a second position (Fig. 12F), at which the distal ends of said arms are separated by a second distance, the second distance being greater than the first

distance; and a shank-like element 228 associated with said head such that relative movement of said shank-like element and said head causes said arms to move from said first position toward said second position, and wherein the distal ends of the arms are adapted to hold and position said joining elements for making an anastomosis between the hollow structures. See figures 12C, 12E-F.

A proximal portion of each said arm is attached to an attachment member 218.

Relative movement of the head and shank-like elements expand the arms radially outwardly, relative to an axis of the shank-like element. Cf. figures 12E, 12F.

The arms expand from the first to the second position with some degree of deformation.

The device further comprises a "part" 228a located proximate to a distal end of the shank-like element for causing movement of the arms from the first position toward the second position.

The part comprises a surface portion in engagement with each said arm such that relative movement between the shank-like element and the head results in movement of the arms from the first position toward the second position. See Fig. 12E.

The device further comprises a detainer (204 or 228a) for controlling movement of the joining elements.

The detainer 204 comprises a plurality of surface portions positioned to engage surface portions of said joining elements to thereby limit the movement of the joining elements relative to the detainer. See Fig. 12E.

The detainer 228a is axially movable relative to the arms.

Axial movement of the detainer results in positioning the joining elements for making an anastomosis by engagement between a surface of each joining element and a surface of each arm. Cf. figures 12D, 12F.

The surface portions of the arms which engage the joining elements are arranged such that the joining elements deform towards a joining position as the detainer is moved axially relative to the arms. Cf. figures 12D-12F. See col. 12, lines 26-30.

The surface portions of the detainer are arranged such that the joining elements can become disengaged from the detainer when the joining elements are in the joining position (at the end of the joining process).

The detainer 204 further comprises a plurality of surface portions positioned to limit the extent of movement of the arms. Fig. 12E.

The surface portions form part of the detainer 204 and part of the head 202.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 15 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 26 of U.S. Patent No. 6,485,496. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one having ordinary skill in the art to equate a radially expandable head adapted to move joining elements from a starting position to a joining position with a head having arms that move from a first position to a second position.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Balazs, U.S. 5,669,918, disclosing an anastomosis device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

January 23, 2007



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER